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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/426,792	10/22/1999	DENNIS T. MANGANO	27116-701.301	2354

21971 7590 11/07/2005

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 11/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/426,792	MANGANO, DENNIS T.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 50-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 50-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9-14-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The finality of the last Office Action is withdrawn.

Applicant's Amendment filed September 14, 2005 is acknowledged. Claims 1-6, 15, 16 and 50-54 remain under consideration.

An Information Disclosure Statement filed September 14, 2005 is further acknowledged and has been reviewed.

Applicant's arguments with respect to claims 1-4, 6, 15, 16, 50, 53 and 54 that were rejected in the last Office Action under 35 U.S.C. 103 have been considered but are moot in view of the new ground of rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 15, 16 and 50-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matangi et al., Can. J. Cardiology.

Matangi teaches the intravenous administration of the β_1-adrenergic blocking agent atenolol within 3 hours of the completion of surgery in patients who have undergone coronary artery bypass grafting. Atenolol therapy was thereafter continued daily for eight days. However, safe and effective long-term therapy with atenolol is well established in the prior art. Cardiovascular status was ascertained via holter monitor analysis which would indicate heart rate and the absence of heart failure. As required by claim 50, risk factors in the patient population under consideration are disclosed in Table 2, page 230. The claims differ with respect to the recitation "administered near

the maximum effective dose". Based on body weight, renal or hepatic status and other physiological conditions, a 50 mg dose may be the maximum effective dose for some patients. There are differences in bioavailability following oral administration, metabolism and excretion among the β_1-adrenergic blocking agents. Further, the determination of an optimal "near maximum effective dose", as well as the determination of an optimal post-procedure daily regimen for administration of the β_1-adrenergic blocking agent, are easily determined by one skilled in the art through no more than minimal routine experimentation. A dose higher than 100 mg is unlikely to produce any further benefit. The maximum dosage of atenolol for a person with a creatinine clearance of 15-35 ml/min is 50 mg daily, while the maximum dosage for a person with a creatinine clearance less than 15 ml/min is 50 mg every other day. A dosage of 100 mg/day orally or 10 mg bid intravenously is conventional. The recitation "within 3 hours of the completion of surgery" encompasses administration "immediately after surgery". Achieving a heart rate greater than or equal to 65 bpm, a systolic blood pressure greater than or equal to 100 mm Hg and no evidence of congestive heart failure, third degree block or bronchospasm would reasonably be considered desirable therapeutic goals.

No claim is allowed.

Kataria et al., J. Cardiothoracic Anesth., is cited to show further the state of the art with respect to administration of a beta-blocker during emergence from anesthesia.

Applicant's submission of an Information Disclosure Statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on September 14, 2005 prompted the

new ground of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

November 3, 2005

Phyllis G. Spivack

1614

PHYLLIS SPIVACK
PRIMARY EXAMINER